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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,492

Applicant(s)

HENLEY, E. C.

Examiner

Ganapathy Krishnan

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/25/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 5/25/2006 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. New Claims 16-20 have been added.
2. Claim 1 has been amended.
3. Remarks drawn to rejections under 35 USC 112, second paragraph, double patenting and 102.

Claims 1-20 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 15 and 18 are rejected under 35 USC 112, second paragraph is being maintained for reasons of record. It is not clear what all are included in the recitation soy protein material. The definition of the said terms should be recited in the claims.

Double Patenting

The obviousness-type double patenting rejection is being maintained for reasons of record. The instant application has a common inventor with the '366 patent.

Claim Rejections - 35 USC § 102

The rejection of claims 1-15 as being anticipated by Potter et al (US 6,326,366) has been overcome by amendment of instant claim 1, wherein the method recites administration of a composition comprising the active agent is not administered in combination with estrogen.

The following rejection is made of record, necessitated by amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelly et al (WO 98/08503).

Kelly et. al teach a method prophylaxis and treatment of urinary incontinence using a composition comprising genestein (page 6, lines 6-11). In formula (I) (page 1) of Kelly when Z is H, R1 is H, R2 is OH, W is H and A and B taken together is the structure at the bottom left at page 1 and Y is OR7 and R7 is H, reduces to genistein. This reads on limitations of instant claims 1, 6 and 7 (source of isoflavone doesn't matter). The amount of the active agent used in the composition in general is 0.1 to 2g (page 9, lines 12-16). This reads on the limitations of instant claims 2-5. Kelly et al teach compositions of the compounds of their invention suitable for oral, rectal, optical buccal, parenteral and transdermal administration. The formulations include capsules tablets suspension, solutions excipients (page 9, line 18 through page 12, line 5). This reads on instant claims 8-13. The active agents may be provided with foodstuff, health

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bars and desserts (page 12, lines 7-11). This reads on instant claim 14. The composition used in the method is for administration to humans. This reads on instant claims 16-17.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al (WO 98/08503) in combination with Potter et al (US 6,326,366).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Kelly et. al teach a method prophylaxis and treatment of urinary incontinence using a composition comprising genestein as elaborated above. Kelly et al do not teach the use of a composition comprising an isoflavone and soy protein material.

Potter et al, drawn to treatment of urinary incontinence using isoflavones teach that soy materials like soy extracts and hulls are a good source of other isoflavones like glycerin and their glycosides, which are also useful in treating incontinence (col. 714-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a composition comprising isoflavones in combination with soy protein material in a method of treatment as instantly claimed since such a method using the active agents is seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to use a composition as instantly claimed in a method as instantly claimed since soy protein material is also the source of other isoflavone and their glycosides and using a composition comprising soy protein materials will have an additive effect in the said treatment.

Conclusion

Claims 1-20 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

***GK


Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623